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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/960,706  | 09/24/2001  | William E. Munger    | 044921-5029-01      | 4547             |
| 9629  | 7590        | 11/22/2005           | EXAMINER            |                  |
| MORGAN LEWIS & BOCKIUS LLP<br>1111 PENNSYLVANIA AVENUE NW<br>WASHINGTON, DC 20004 |             |                      | MORAN, MARJORIE A   |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1631                |                  |

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/960,706 | <b>Applicant(s)</b><br>MUNGER ET AL. |  |
|                              | <b>Examiner</b><br>Marjorie A. Moran | <b>Art Unit</b><br>1631              |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 57-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 57-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/8/05 has been entered.

Claims 57-69 are pending. All rejections of claims 32-56 are hereby withdrawn in view of cancellation of those claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

A computer system comprising a user interface for entering a first experimental dataset comprising statistical values, as recited in new claim 57, is new matter. Original claim 32 recited a computer system comprising a user interface for *viewing* information,

Art Unit: 1631

but did not recite any kind of interface for *entering* information, specifically statistical values. It is noted that an “old-fashioned” CRT screen may be used to view information, but is not configured for entry of information, therefore a recitation of a “user-interface” is not necessarily a disclosure for an interface capable of data-entry. Original claim 39, which is nonelected, was directed to a method of using a computer system comprising comparing gene expression levels, but did not recite any step of entering the expression level values, or any other statistical information, into a computer, such that the step necessarily required a user interface. Applicant points to pages 14-15 of the specification for support for the newly filed claims. Page 14 of the originally filed specification, starting at line 29, does provide support for relational databases comprising sequence information. Page 15, lines 10-13 provides support for linked databases, and lines 14-19 disclose that “any appropriate computer platform” may be used to perform data comparisons. Page 15 does not disclose data entry nor a user interface, specifically, anywhere. The originally filed specification does not provide support for a user interface for, nor a step of, entering an experimental dataset of statistical values which are a measure of differential expression anywhere.

Software “to generate a second experimental dataset”, as recited in part (c) of claim 57, is also new matter. The original claims did not recite “software” anywhere. Page 15 of the originally filed specification discloses a computer platform, generally, but does not specifically disclose software configured to perform any specific steps. Page 21 of the originally filed specification, lines 24-32, discloses software and software-based methods for analysis of microarray information and data mining, but does not

Art Unit: 1631

specifically disclose software “for comparing statistical values” nor which is used to “generate a second experimental dataset...” In fact, the originally filed specification does not teach generation of a second experimental dataset indicative of the presence or absence of BPH anywhere.

A control sample comprising “at least one”, “at least two” or “at least ten” nucleic acid molecules, as recited in claims 57 (part (a)), and in claims 68-69, is new matter. Original claims 32 and 33 recited a computer system comprising information identifying expression levels of at least two genes in Tables 1-6, or Table 5, specifically. The original claims did not recite control samples versus test samples. Applicant points to page 3 of the originally filed specification for support for “at least ten genes.” Page 3 discloses that the expression levels “at least 2,3,4,5,6,7,8,9, 10 or more genes from any one of Tables 1-6” may be detected; pages 2-3 disclose screening a database comprising “two or more genes” from the Tables. The specification does not disclose a database or computer system comprising data from specific numbers of control samples anywhere.

For all the reasons set forth above, the claim recite new matter and are rejected.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571)

Art Unit: 1631

272-0720. The examiner can normally be reached on Mon,Wed: 7-1:30; Tue,Thur:  
7:30-6; Fri 7-3:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran  
Primary Examiner  
Art Unit 1631

*Marjorie A. Moran*  
11/14/05